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Paper ~~21~~ 32

Filed by: Trial Section Motions Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GLAXO WELLCOME INC.

Junior Party
(Patents 5,545,403, 5,545,404,
and 5,545,405)

v.

SHMUEL CABILLY,
HERBERT L. HEYNEKER, WILLIAM E. HOLMES,
and RONALD B. WETZEL

Senior Party
(Application 08/909,611)

Patent Interference No. 104,532

Before SCHAFER, TORCZON, and GARDNER-LANE, Administrative Patent Judges.

GARDNER-LANE, Administrative Patent Judge.

DECISION ON PRELIMINARY AND OTHER MOTIONS AND FINAL JUDGMENT

I. INTRODUCTION

The interference was declared on 15 May 2000 between junior party Glaxo Wellcome Inc. ("Glaxo") and senior party Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthurs D. Riggs, and Ronald B. Wetzel ("Cabilly"). A hearing on preliminary and other motions was held on 18 September 2001.

Brief summary of the involved technology

The invention defined by Count 1 is broadly directed to a method of treatment using antibodies expressed by Chinese hamster ovary ("CHO") cells. The antibodies may be produced by transfecting CHO cells with two separate vectors. One vector is capable of expressing the heavy chain of the desired antibody and the other vector is capable of expressing the light chain of the desired antibody (5,545,403 ("'403") at 3:4-8). The heavy and light chains assemble within the CHO cell and a functional antibody is secreted into the cultural medium ('403 at 5:33-37). The CHO cells may be used to express chimeric antibodies comprising a human constant region and a non-human variable region. These chimeric antibodies are said to result in antibodies that are less likely to elicit an unintended immune response in a human to be treated (Exh. 2103 at 11-12).

Diseases including cancer and T-cell mediated disorders, are said to be treatable with the CHO cell expressed antibodies ('403 at 8-18).

The parties seem to agree that the antibodies that are appropriately the subject matter of the interference are glycosylated by the CHO cells expressing them (Paper 51 at 5-6 and Paper 106 at 12). All the Glaxo involved claims expressly state that the claimed antibodies have been glycosylated by CHO cells. Glaxo discloses that antibodies glycosylated by CHO cells have

"antigen binding capability and effector functionality" ('403 at 5:8-61). Some, but not all, of the Cabilly claims expressly state that the claimed antibodies have been glycosylated by CHO cells. The Cabilly disclosure recognizes that antibodies expressed in mammalian cells would be expected to be glycosylated (Exh. 2103 at 4:18-21 and 45:26-28).

Brief summary of the decision

We grant that portion of Glaxo preliminary motion 5 seeking to substitute proposed Count 2 and deny or dismiss the remaining portion of Glaxo preliminary motion 5. We deny or dismiss all the remaining Glaxo preliminary and other motions. For reasons that we shall explain below, we do not find it necessary to decide any Cabilly preliminary or other motion. Thus, we dismiss each Cabilly preliminary and other motion.

Because Glaxo did not allege a conception date earlier than the filing date of a Cabilly priority benefit application, we enter final judgment against Glaxo.

II. FINDINGS OF FACT

The record supports the following findings of facts and any findings of facts set forth in the discussion portion of this decision by at least a preponderance of the evidence.

The junior party

1. Glaxo is involved in the interference on the basis of the following three patents:

   a. 5,545,403 ("'403"), which issued on 13 August 1996 from application 08/155,864, filed 23 November 1993.

   b. 5,545,404 ("404"), which issued on 13 August 1996 from application 08/335,400, filed 3 November 1994.

c. 5,545,405 ("'405"), which issued on 13 August 1996 from application 08/335,401, filed 3 November 1994.

2. Glaxo is said to be the assignee of the three patents (Paper 9).

3. Martin J. Page and James Scott Crowe are said to be coinventors of the subject matter claimed in the '403, '404 and '405 patents (Paper 46).[1]

The senior party

4. Cabilly is involved in the interference on the basis of its 08/909,611 ("'611") application which was filed 12 August 1997.

5. Genentech, Inc. is said to be the assignee of the '611 application (Paper 5).

6. Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel are said to be coinventors of the subject matter claimed in the '611 application.

The count

7. The sole count of the interference, Count 1, is as follows (Paper 1 at 49):

A method according to claim 1 of 5,545,403

or

a method according to claim 1 of 5,545,404

or

a method according to claim 1 of 5,545,405

or

a method according to any of claims 53, 55, or 56 of 08/909,611.

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[1] Glaxo points out that the Notice Declaring Interference (Paper 1) did not list James Scott Crowe as an inventor as to the '403 patent (Paper 46).

8. Claim 1 of the '403 patent reads as follows:

1. In a method for treating a human suffering from a disease or disorder comprising administering a therapeutically effective amount of a whole glycosylated recombinant human, chimeric or CDR[2]-grafted or bispecific antibody effective in treating said disease or disorder in said human, wherein the improvement comprises an antibody glycosylated by a [C]hinese hamster ovary cell.

9. Claim 1 of the '404 patent reads as follows:

1. In a method for treating a human suffering from a T-cell mediated disorder comprising administering a therapeutically effective amount of a whole glycosylated recombinant human, chimeric, CDR-grafted or bispecific antibody effective in treating said disorder, wherein the improvement comprises an antibody glycosylated by a Chinese hamster ovary cell.

10. Claim 1 of the '405 patent reads as follows:

1. In a method for treating a human suffering from cancer by administering a therapeutically effective amount of a whole glycosylated recombinant human, chimeric, CDR grafted or bispecific antibody effective in treating said cancer, wherein the improvement comprises an antibody glycosylated by a Chinese hamster ovary cell.

11. Claims 53, 55, and 56 of the '611 application read as follows:

53. In a method for treating a human suffering from a disease comprising administering a glycosylated recombinant human, chimeric, hybrid, altered or univalent antibody to said human in an amount effective in treating said disease in said human, wherein the improvement comprises administering an antibody glycosylated by a Chinese hamster ovary cell to said human.

55. In a method for treating a human suffering from an attack by a substance or organism comprising administering a glycosylated recombinant human, chimeric, hybrid, altered, or univalent antibody to said human in an amount effective in treating said attack of said human, wherein the improvement comprises administering an antibody glycosylated by a Chinese hamster ovary cell to said human.

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[2] We understand "CDR" to be "complementarity determining regions."

56. A method for treating a subject suffering from an attack by a substance or organism, comprising administering an antibody which binds to said substance or organism in an amount effective to combat said attack, wherein said antibody is a recombinant human, chimeric, hybrid, altered, or univalent antibody expressed by a Chinese hamster ovary cell.

Priority benefit

12. Glaxo is accorded benefit for the purpose of priority of the filing dates of the following applications (Paper 1 at 45-47):

a. 08/046,893, filed 15 April 1993,

b. 07/943,146, filed 10 September 1992[3], and

c. 07/777,730, filed 16 October 1991

13. Cabilly is accorded benefit for the purpose of priority of the filing dates of the following applications (Paper 1 at 48):

a. 07/205,419 ("'419"), filed 10 June 1988 and issued as patent 6,331,415 on 18 December 2001[4], and

b. 06/483,457 ("'457"), filed 8 April 1983 and issued as patent 4,816,567 on 28 March 1989.

Glaxo preliminary statement

14. In its preliminary statement, Glaxo states that its conception of the invention of Count 1 "was first introduced into the United States at least as early as June 25, 1989" and that an actual reduction to practice in the United States of the invention of Count 1 "was first introduced into the United States at least as early as September 10, 1990" (Paper 45 at 3).

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[3] The Notice Declaring Interference (Paper 1) indicates a 10 October 1992 filing date. However, USPTO records indicate a filing date of 10 September 1992

[4] The patent issued after the interference was declared and thus is not listed in the Notice Declaring Interference (Paper 1).

15. Thus Glaxo does not allege a date of conception that is earlier than the 10 June 1988 filing date of Cabilly's '419 priority benefit application for the subject matter of Count 1.

Claim designations

16. All the claims of each involved patent or application were designated as corresponding to Count 1 (Paper 1 at 49).

Glaxo preliminary motions

17. Glaxo filed the following fourteen preliminary motions:

a. Glaxo preliminary motion 1 under 37 CFR § 1.633(g) attacking the priority benefit accorded to Cabilly for the 8 April 1983 filing date of the '457 application (Paper 47).

b. Glaxo preliminary motion 2 under 37 CFR § 1.633(g) attacking the priority benefit accorded to Cabilly for the 10 June 1988 filing date of the '419 application (Paper 48).

c. Glaxo preliminary motion 3 under 37 CFR § 1.633(a) for judgment that the '611 claims are unpatentable under 35 USC § 112, ¶1, due to lack of written description (Paper 49).

d. Glaxo preliminary motion 4 under 37 CFR § 1.633(c) (4) to have Cabilly claims 56-60 designated as not corresponding to Count 1 (Paper 50).

e. Glaxo preliminary motion 5 under 37 CFR § 1.633(c)(1) to substitute its proposed Count 2 for Count 1 (Paper 51).

f. Glaxo preliminary motion 6 under 37 CFR § 1.633(c)(4) to have claim 2 of Glaxo's '405 patent designated as not corresponding to Count 1 (Paper 52).

g. Glaxo preliminary motion 7 under 37 CFR § 1.633(c)(4) to have claims 3, 5, and 7 of Glaxo's '403 patent, claims 3-6 of Glaxo's '404 patent, and claim 5 of Glaxo's '405 patent designated as not corresponding to Count 1 (Paper 53).

h. Glaxo preliminary motion 8 under 37 CFR § 1.633(c)(4) to have claims 2, 4, and 6 of Glaxo's '403 patent and claims 3-5 and 7 of Glaxo's '404 patent designated as not corresponding to Count 1 (Paper 54).

i. Glaxo preliminary motion 9 under 37 CFR § 1.633(c)(4) to have claims 3-5 and 7 of Glaxo's '405 patent designated as not corresponding to Count 1 (Paper 55).

j. Glaxo preliminary motion 10 under 37 CFR § 1.633(a) for judgment that the Cabilly claims are unpatentable under 35 USC 112, ¶1, due to lack of an enabling disclosure (Paper 56).

k. Glaxo preliminary motion 11 under 37 CFR § 1.633(b) for judgment that there is no interference-in-fact (Paper 57).

l. Glaxo contingent preliminary motion 12 attacking any priority benefit to be accorded to Cabilly for the filing date of the '457 application as to proposed Count 2 (Paper 58).

m. Glaxo contingent preliminary motion 13 attacking any priority benefit to be accorded to Cabilly for the filing date of the '419 application as to proposed Count 2 (Paper 59).

n. Glaxo contingent preliminary motion 14 under 37 CFR § 1.637(f) seeking priority benefit of earlier filed Glaxo applications as to proposed Count 2 (Paper 60).

Cabilly preliminary motions

18. Cabilly filed the following nine preliminary motions:

a. Cabilly preliminary motion 1 under 37 CFR § 1.633(a) for judgment that the claims of the '403, '404, and '405 Glaxo patent are unpatentable under 35 USC § 102 or § 103 in view of "the Shively work" (Paper 65).

b. Cabilly preliminary motion 2 under 37 CFR § 1.633(a) for judgment that the claims of the '405 patent are unpatentable under 35 USC § 102 or § 103 in view of prior art cited by Glaxo (Paper 66).

c. Cabilly preliminary motion 3 under 37 CFR § 1.633(a) for judgment that the claims of the '403, '404, and '405 Glaxo patents are unpatentable under 35 USC § 102 or § 103 in view of "the Capon work" (Paper 67).

d. Cabilly preliminary motion 4 under 37 CFR § 1.633(a) for judgment that the claims of the '403, '404, and '405 Glaxo patents are unpatentable under 35 USC § 112, ¶1, for failure to provide an enabling disclosure (Paper 68).

e. Cabilly preliminary motion 5 under 37 CFR § 1.633(a) for judgment that the claims of the '403, '404, and '405 Glaxo patents are unpatentable under 35 USC § 102(f) on the basis that Martin J. Page is not the inventor of the claimed subject mater (Paper 69).

f. Cabilly preliminary motion 6 under 37 CFR § 1.633(a) for judgment that the claims of the claims of the '403, '404, and '405 Glaxo patents are unpatentable under 35 USC § 102(a), 35 USC § 102(b), or 35 USC § 103, in view of clinical trials conducted in 1989-1991 (Paper 70).

37 CFR § 1.633(i) and (j) preliminary motions

g. Cabilly preliminary motion 7 under 37 CFR 1.633(c)(2) to add claims 61-67 to the '611 application (Paper 75).

h. Cabilly contingent preliminary motion 8 under 37 CFR 1.633(f) to be accorded priority benefit for the filing date of the '419 application for claims 61-67 (Paper 76).

i. Cabilly contingent preliminary motion 9 under 37 CFR § 1.633(f) to be accorded priority benefit for the filing date of the '457 application for claims 61-67 (Paper 77).

Other Glaxo motions

19. Glaxo filed twelve miscellaneous motions.

20. Glaxo miscellaneous motions 1-4 and 6-9 have been decided. In particular:

Glaxo miscellaneous motion 1 was denied (Paper 39),

Glaxo miscellaneous motions 2 and 3 were denied (Paper 99),

Glaxo miscellaneous motion 4 was granted (Paper 128), and

Glaxo preliminary motions 6, 7, and 9 were granted (Paper 163).

21. Glaxo miscellaneous motion 5 is contingent upon the denial of Glaxo miscellaneous motion 4 (Paper 121 at 2) and thus is DISMISSED as moot.

22. Glaxo miscellaneous motion 8 was returned to Glaxo (Paper 163) because it was said to be replaced by Glaxo miscellaneous motion 9 and thus is DISMISSED as moot (Paper 142 at 2).

23. Glaxo miscellaneous motions 10, 11, and 12 are treated as motions to suppress evidence (Paper 179).

Other Cabilly motions

24. Cabilly filed Cabilly miscellaneous motion 1 (Paper 81) and a first motion to suppress evidence (Paper 167) and a second motion to suppress evidence (Paper 208).

25. Cabilly miscellaneous motion 1 was granted (Paper 85).

Glaxo's preliminary motion to substitute proposed Count 2

26. Glaxo filed its preliminary motion 5 seeking to substitute proposed Count 2 for Count 1.

27. Proposed Count 2 reads as follows (Paper 51 at 2):

> The invention of claim 1 of U.S. Patent 5,545,403; Claim 1 of U.S. Patent 5,545,404; Claim 1 of U.S. Patent 5,545,405; Claim 53 of Cabilly Application No. 08/909,611; or Claim 55 of Cabilly Application No. 08/909,611.

28. Proposed Count 2 is the same as Count 1 except it eliminates that portion of Count 1 directed to '611 claim 56.

29. '611 claim 56 does not expressly require glycosylation of the antibodies used in treatment or the treatment of a human (Paper 51 at 5).

30. Glaxo argues that glycosylation by CHO cells and the selection of a human as the subject for treatment would not have been obvious to one having ordinary skill in the art (Paper 51 as 12-13).

31. According to Glaxo, Cabilly should not be accorded priority benefit of the '419 application for proposed Count 2 for the same reasons Cabilly should not be accorded priority benefit of the '419 application for Count 1 (Paper 51 at 16-17).

Glaxo's preliminary motions involving Cabilly's written description

32. Glaxo has filed its preliminary motion 3 moving for judgment that the Cabilly involved claims are unpatentable based on a lack of written description under 35 USC § 112, ¶ 1.

33. Glaxo acknowledges that the involved '611 Cabilly application is essentially the same as Cabilly's '419 application (Paper 203 at 14). When we wish to refer to the '611 and the '419 application collectively, we will refer to the "Cabilly applications".

34. Glaxo makes substantially the same arguments in its preliminary motion 3 as it does in that portion of its preliminary motion 5 urging that Cabilly should not be accorded priority benefit of the '419 application for proposed Count 2.

35. In particular, Glaxo argues that the '419 disclosure does not contain a written description of an embodiment of the invention falling within Count 1. We note that Glaxo does not argue that the '419 disclosure lacked enablement for an embodiment within the scope of proposed Count 2 (Paper 51 at 17).[5]

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[5] We also note the difference between Glaxo's position in its preliminary motion 1 (attacking the priority benefit accorded to Cabilly for it's '457 application) and Glaxo's position in its preliminary motion 5. In its preliminary motion 1, Glaxo argues that the '457 disclosure lacks written description for an embodiment within the scope of Count 1 **and** that Cabilly's '457 disclosure "does [did] not enable one skilled in the art to make and/or use the invention of the Count or an embodiment of an invention falling within the Count without undue experimentation" (Paper 47 at 4). Our understanding is that the difference in Glaxo's position is based upon a change in the level of skill in the art between the filing date of the '457 application and the filing date of the '419 application (see, e.g., Exh. 1120 at 75:18-76:3 and Paper 203 at 16-17).

Glycosylation by CHO cells

36. Glaxo argues that neither of the Cabilly applications describes antibodies that are glycosylated by CHO cells (Paper 49 at 11-12 and Paper 51 at 21-25).

37. Glaxo argues that "it is possible that an antibody expressed by a CHO cell might not be glycosylated" and "[t]herefore even if the antibody was expressed in a CHO cell, it does not necessarily follow that the antibody would be glycosylated" (Paper 49 at 11-12 and Paper 51 at 21-22).

38. Cabilly argues that the Cabilly applications disclose antibodies expressed by CHO cells and that the Cabilly applications disclose that those antibodies would be glycosylated (Paper 106 at 5).

39. The examples provided by the Cabilly applications are directed to the expression of antibodies by *E.coli* cells (Exh. 2103 at 30-53).

40. Evidence pointed out to us indicates that an *E.coli* cell will not ordinarily glycosylate a protein it expresses (Exh. 2012 at ¶17).

41. The Cabilly applications indicate that a mammalian cell would be expected to produce antibodies that are glycosylated. For example, the Cabilly applications state that:

> Heavy chain from mammalian cells is expected to be slightly heavier than *E.coli* material due to glycosylation in the former (Exh. 2103 and Exh. 2102 at 45:26-28)

and that

> Third, both hybridomas and B cells inevitably produce certain antibodies in glycosylated form (Melchers, F., Biochemistry, 10: 653 (1971)) which, under some circumstances, may be undesirable (Exh. 2103 and Exh. 2102 at 4:18-21).

42. The only specific mention of CHO cells found in the Cabilly applications is as follows (Exh. 2103 and Exh. 2102 at 18: 8-10):

> Examples of such useful host cells [for expressing antibodies] are VERO and HeLa cells, Chinese hamster ovary (CHO) cell lines, and WI38, BHK, COS-7 and MDCK cell lines.

Dr. Youles' testimony regarding glycosylation:

43. In its preliminary motions 3 and 5, Glaxo points to the testimony of Dr. Richard J. Youle (Exh. 2012) in support of its arguments regarding the insufficient written description in the Cabilly applications, but directs us to no specific portion of the testimony.

44. In its reply to Cabilly's opposition to its preliminary motion 3, Glaxo states that the entire Youle declaration should be considered but that "since Cabilly suggests that GWI[6] must point to particular paragraphs, GWI will point to ¶¶ 27, 28, 33-38 of Exhibit 2012 [Dr. Youle's declaration]" (Paper 154 at 7-8).

45. From our own review of Dr.Youle's testimony, we note the following:

a) Dr. Youle testified that: "antibodies expressed by the *E. coli* cells described in the Cabilly application[7] were not glycosylated, since it is well known that prokaryotic organisms, such as E.coli and other bacteria, do not produce glycosylated antibodies" (Exh. 2012 at ¶17);

b) Dr. Youle testified that, "[s]ince Cabilly cautions that glycosylated antibodies can be 'undesirable', I would be reluctant to attempt to use eukaryotic organisms to express

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6 We understand "GWI" to be Glaxo.

7 Dr. Youle seems to be referring to the '457 application at this point in his testimony but later in his testimony indicates that his conclusions regarding written description also apply to the '419 application (Exh. 2012 at ¶¶33-34).

recombinant antibodies in order to avoid possible undesirable effects of glycosylation on antibody production" (Exh. 2012 at ¶ 23);

c) Dr. Youle testified that, in CHO cells expressing antibodies, it would have been possible to take steps to either inhibit glycosylation or to remove the sugar groups after glycosylation (Exh. 2012 at ¶¶31-32) ; and

d) Dr. Youle testified that in mammalian cells, "the addition of a special 'leader sequence' would be required to steer the protein to the secretory pathway" that would be necessary "for any hope of proper glycosylation of the antibodies." According to Dr. Youle, the Cabilly application does not teach the addition of such a leader sequence (Exh. 2012 at ¶ 18).

A therapeutic method

46. Glaxo argues that the Cabilly applications do not teach a therapeutic method as required by the '611 claims and proposed Count 2 (Paper 49 at 9-10 and Paper 51 at 20-21).

47. Proposed Count 2 is directed to a method of treating one of the following:

a. a human suffering from a disease or disorder ('403 claim 1)

b. a human suffering from a T-cell mediated disorder ('404 claim 1)

c. a human suffering from cancer ('405 claim 1)

d. a human suffering from a disease ('611 claim 53)

e. a human suffering from an attack by a substance or organism ('611 claim 55)

48. In a first portion of the application entitled "Background of the Invention", the Cabilly applications state that (Exh. 2103 and Exh. 2102 at 3:26 to 4:2):

> In another important use, antibodies can be directly injected into subjects suffering from an attack by a substance or organism containing the antigen in question to combat this attack. This process is currently in its experimental stages, but its potential is clearly seen. Third, whole body diagnosis and treatment

> is made possible because injected antibodies are directed to specific target disease tissues, and thus can be used either to determine the presence of the disease by carrying with them a suitable label, or to attack the diseased tissue by carrying a suitable drug.

49. In a second portion of the application entitled "Detailed Description", the Cabilly applications state that chimeric antibodies having human constant regions are "less likely to elicit an immune response from a human subject when the antibodies are injected than would the constant region from a non-human source" (Exh. 2103 and Exh. 2102 at 11:26-12:12).

50. In its preliminary motion 5, Glaxo argues that (Paper 51 at 20):

> Dr. Youle states that Cabilly does not describe the invention as being directed to a therapeutic method [Exhibit 2012]; and that
>
> Dr. Youle and Dr. Vitetta both concluded that the 1983 and 1988 Cabilly applications do not describe the invention of Count 1 or any claims that correspond thereto [Exhibit 2012 and 2028].

51. In its preliminary motions 3 and 5, Glaxo does not point to specific portions of the testimony of Dr. Youle or Dr. Vitetta in support of its position that the Cabilly applications do not describe a therapeutic method.

52. Glaxo points to some specific portions of the testimony of Dr. Youle and Dr. Vitetta in its reply to Cabilly opposition 3 (FF[8] 44 and Paper 154 at 7-8).

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[8] Finding of fact.

III. DISCUSSION

A. Procedural issues

We note that each party argues that the other party, at times, fails to comply with proper procedure in presenting its arguments in its preliminary motions. Both parties point to our decision in LeVeen v. Edwards, 57 USPQ2d 1406 (BPAI (ITS) 2000).

As noted by Glaxo, LeVeen was decided after the initial preliminary motions were filed in the interference (Paper 154 at 3). However, to the extent Glaxo is arguing that LeVeen should not apply in the present interference, we note that the decision in LeVeen did not present any new procedural requirements for interferences. For example, LeVeen discussed requirements found in the Notice Declaring Interference (Paper 1).

One portion of LeVeen, set out below, discusses improper incorporation by reference, 57 USPQ at 1412:[9]

> The NOTICE DECLARING INTERFERENCE explicitly precludes incorporation by reference of arguments. There are numerous reasons why an agency, in general or in a particular case, may preclude incorporation by reference in papers presented to the agency. First, an incorporated argument may be overlooked (Paper 1, page 10 n.7). Second, incorporation of arguments is not consistent with efficient decision making (Paper 1, page 10 n.7). Essentially, incorporation by reference is an inappropriate role-shifting technique which makes it a decision maker's job to (1) scour the record, (2) come up with some theory which supports a party's case and (3) articulate a rationale in an opinion supporting the rationale without giving an opponent a reasonable chance to address the rationale. Third, through incorporation by reference an attorney can avoid page limitations applicable to motions (Paper 1, page 27 ¶ 28). Compare DeSilva v. DiLeonardi, 181 F.3d 865, 866-67 (7th Cir. 1999) ("[a]doption by reference amounts to a self-help increase in the length of the * * * brief. * * * [I]ncorporation by reference is a

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[9] ¶ 13 of the Notice Declaring Interference states that (Paper 1 at 9):

> Arguments presented in one paper shall not be incorporated by reference to another paper.

pointless imposition on the court's time. A brief must make all arguments accessible to the judges, rather than ask them to play archaeologist with the record.").

LeVeen also discusses why it is improper for a party to point to a lengthy exhibit without identifying a specific portion of the exhibit relied upon. LeVeen states at 57 USPQ at 1413:

> We decline to search the prior art to see if somehow it might support Edwards' anticipation theory. Compare Clintec Nutrition Co. v. Baxa Corp., 44 USPQ2d 1719, 1723 n.16 (N.D. Ill. 1997), which notes that where a party points the court to multipage exhibits without citing a specific portion or page, the court will not pour over the documents to extract the relevant information, citing United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991) (judges do not hunt for truffles buried in briefs); Ernst Haas Studio, Inc. v. Palm Press, Inc., 164 F.3d 110, 111-12, 49 USPQ2d 1377, 1378-79 (2d Cir. 1999) ("Appellant's Brief is at best an invitation to the court to scour the record, research any legal theory that comes to mind, and serve generally as an advocate for appellant. We decline the invitation. Although the issues raised are complex, appellant's main Brief is only nine pages long and does not cite a single statute or court decision related to copyright. Nor does it present a coherent legal theory, even one unsupported by citation to authority that would sustain the complaint."); Winner International Royalty Corp. v. Wang, 202 F.3d 1340, 1351, 53 USPQ2d 1580, 1589 (Fed. Cir. 2000) (We agree with Winner that the district court did not abuse its discretion in allowing allegedly late-disclosed witnesses to testify. Such witnesses were never even identified by Wang in his opening brief * * *. Under such circumstances, we will not search the record on the chance of discovering which witnesses Wang was complaining of and then determine whether the district court abused its discretion. Thus, whichever witnesses Wang was alluding to, admission of their testimony cannot be said to be an abuse of discretion based on the vague arguments made by Wang on appeal).

In deciding the motions before us, we will not consider material that a party attempts to incorporate by reference for the reasons set forth in LeVeen. Therefore, in deciding a particular motion before us, we will not look to another motion to make a party's case for it even if the party directs us to the other motion. For example, in its preliminary motion 5, Glaxo states that "[t]he remaining claims of the '403, '404 and '405 patents should not correspond to Proposed

Count 2 for the reasons set forth in GWI Preliminary Motions 6-9". We have not considered the arguments from preliminary motions 6-9 as part of preliminary motion 5 (Paper 51 at 4). Our decision granting or denying a motion is based solely on the arguments and specific evidence pointed out to us in the motion before us.

Another example of an improper attempt to incorporate material by reference is found in Glaxo preliminary motion 5. Glaxo states that "[t]he legal requirements for written description are summarized in Exhibit 2126"(Paper 51 at 17). We do not consider the arguments presented in Exhibit 2126 in deciding Glaxo preliminary motion 5 unless the arguments are also presented in preliminary motion 5.[10]

Glaxo appears to agree that we should not consider arguments incorporated by reference. For example, Glaxo states that "[e]ven if the APJ were to find the mere mention of an argument set out in another motion incorporation [incorporated] by reference, then the APJ may disregard such statements." Glaxo argues that its preliminary motion 5 has "all arguments necessary to prove GWI's position set out in the body of the motion with appropriate citations to evidence" (Paper 156 at 4).

Moreover, we have not speculated on what portion of an exhibit a party is relying upon where the party has not directed us to a specific portion of the exhibit. Thus, where Glaxo directs us to "the explanations concerning this point in Exhibits 2012 and 2028" (Paper 49 at 11), we have not speculated on which portions of Exhibits 2012 and 2028 Glaxo intended.

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[10] Glaxo does not list Exhibit 2126 as an exhibit relied upon in its preliminary motion 3 arguing that the '611 application lacks written description. (Paper 48 at 1).

B. Glaxo preliminary motions

Summary of the Glaxo preliminary motions

Glaxo's preliminary motion 5 seeks to substitute proposed Count 2 for Count 1. Proposed Count 2 eliminates that portion of Count 1 that does not expressly require glycosylation by CHO cells or the treatment of a human (FFs 28, 29).

A central issue in this interference is whether Glaxo has shown that Cabilly fails to meet the written description requirement of 35 USC § 112, ¶ 1:

(a) for the subject matter of Cabilly's involved claims in the '611 application (argued in Glaxo preliminary motion 3), and

(b) for an embodiment within the scope of proposed Count 2 in the '419 application (argued in Glaxo preliminary motion 5).

For much the same reason Glaxo argues that the Cabilly applications do not provide adequate written description, Glaxo moves for judgment that there is no interference-in-fact (Paper 57).

Glaxo moves for judgment that the claims of Cabilly's '611 application are unpatentable for lack of enablement under 35 USC § 112, ¶1 (Paper 56).

We need not and have not decided the remaining Glaxo preliminary motions for reasons further explained below.

Glaxo preliminary motion 5

In its preliminary motion 5, Glaxo moves to substitute proposed Count 2 for Count 1. Proposed Count 2 is the same as Count 1 except proposed Count 2 excludes Cabilly claim 56.

Cabilly claim 56 does not require the treatment of a subject that is a human or that the antibodies used for treatment be glycosylated (FFs 28, 29).

37 CFR § 1.637(c)(1)(i)-(vii) states that:

> (c) A preliminary motion under § 1.633(c) shall explain why the interfering subject matter should be redefined.
>
> (1) A preliminary motion seeking to add or substitute a count shall:
>
> (i) Propose each count to be added or substituted.
>
> (ii) When the moving party is an applicant, show the patentability to the applicant of all claims in, or proposed to be added to, the party's application which correspond to each proposed count and apply the terms of the claims to the disclosure of the party's application; when necessary a moving party applicant shall file with the motion an amendment adding any proposed claim to the application.
>
> (iii) Identify all claims in an opponent's application which should be designated to correspond to each proposed count; if an opponent's application does not contain such a claim, the moving party shall propose a claim to be added to the opponent's application. The moving party shall show the patentability of any proposed claims to the opponent and apply the terms of the claims to the disclosure of the opponent's application.
>
> (iv) Designate the claims of any patent involved in the interference which define the same patentable invention as each proposed count.
>
> (v) Show that each proposed count defines a separate patentable invention from every other count proposed to remain in the interference.
>
> (vi) Be accompanied by a motion under § 1.633(f) requesting the benefit of the filing date of any earlier filed application, if benefit of the earlier filed application is desired with respect to a proposed count.
>
> (vii) If an opponent is accorded the benefit of the filing date of an earlier filed application in the notice of declaration of the interference, show why the opponent is not entitled to benefit of the earlier filed application with respect to the proposed count. Otherwise, the opponent will be presumed to be entitled to the benefit of the earlier filed application with respect to the proposed count.

Claim 1 of each of Glaxo '403, '404, and '405 and claims 53 and 55 of Cabilly '611 require antibodies that are glycosylated by the CHO cells expressing them (FFs 8-11). Claim 56 of the '611 application requires antibodies expressed by CHO cells, but does not require that the antibodies be glycosylated.

'611 claim 56 is directed to the treatment of a "subject". Claim 1 of each of Glaxo '403, '404, and '405 and claims 53 and 55 of Cabilly '611 are also directed to a method of treating a "subject" but these claims specify that the subject to be treated is a human.

Since '611 claim 56 is directed to a genus of antibodies (glycosylated and non-glycosylated) and a genus of subjects to be treated (humans and non-humans), the claim is, on its face, broader in scope than the subject matter of proposed Count 2, i.e., claim 1 of Glaxo '403, claim 1 of Glaxo '404, claim 1 of Glaxo '405 , '611 claim 53, or '611 claim. Thus, the subject matter of proposed Count 2 (taken as presumed prior art) anticipates '611 claim 56 and '611 claim 56 is appropriately designated as corresponding to proposed Count 2. See In re Gosteli, 872 F.2d 1008, 1010, 10 USPQ2d 1614,1616 (Fed. Cir. 1989) and 37 CFR § 1.606 and § 1.601(n).[11]

It is appropriate to substitute a narrower count so as to limit the count to a single patentable invention. Lee v. McIntyre, 55 USPQ2d 1406, 1412 (BPAI (ITS) 2000). Thus, it is appropriate to substitute proposed Count 2 if Count 1 encompasses more than a single patentable invention.

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[11] § 1.606 states that a claim that defines the same patentable invention as the count shall be designated as corresponding to the count. § 1.601(n) states that an invention is the same patentable invention as another invention when the invention is anticipated or obvious in view of the other invention. Therefore, a genus claim corresponds to a sub-genus or species count.

The fact that the subgenus of proposed Count 2 is encompassed by the genus of '611 claim 56, does not, by itself, necessarily establish a *prima facie* case that proposed Count 2 is obvious in view of claim 56. In re Baird , 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) . Thus, we determine that Glaxo has made a *prima facie* showing that claim 56 encompasses an invention that is separately patentable from the particular sub-genus or species invention encompassed by proposed Count 2.

Cabilly opposes the substitution of proposed Count 2. Cabilly argues that: (1) "an antibody expressed by CHO mammalian cells according to the teachings of Cabilly would be inherently glycosylated" and (2) Glaxo has not provided evidence that treatment of human subjects is separately patentable from the treatment of other subjects.

Glaxo has shown that it is appropriate to substitute proposed Count 2 because '611 claim 56 does not expressly require that the antibodies used for treatment be glycosylated.

When we give claim 56 its broadest reasonable interpretation, we determine that the antibodies of claim 56 may be glycosylated or non-glycosylated. For example, Dr. Youle testified that under certain circumstances antibodies expressed by CHO cells may not be glycosylated (FF 51c). While we make no determination as to whether the '611 application describes antibodies expressed in CHO cells that are not glycosylated, Glaxo has shown that claim 56 encompasses non-glycosylated antibodies.[12]

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[12] Even if the '611 application does not describe non-glycosylated antibodies expressed in CHO cells, we do not find it appropriate to interpret claim 56 as requiring glycosylation. In re Van Geuns, 988 F.2d 1181, 1186, 26 USPQ2d 1057, 1059 (Fed. Cir. 1993); Enercon GmbH v. ITC, 151 F.3d 1376, 1384, 47 USPQ2d 1725, 1731 (Fed. Cir. 1998) ("[W]hile claims are to be construed in light of the specification, they are not necessarily limited to the specification.")

Glaxo has shown that '611 claim 56 encompasses more than one patentable invention, i.e., glycosylated antibodies and non-glycosylated antibodies. Thus, Glaxo has shown it is appropriate to substitute Glaxo proposed Count 2 for Count 1. Lee v. McIntyre, 55 USPQ2d at 1412. Leaving claim 56 in the Count would permit the parties to submit proofs other than proofs for the interfering subject matter.

We GRANT Glaxo preliminary motion 5 to the extent it seeks to substitute proposed Count 2 for Count 1.

'611 claim designations:

Glaxo states that '611 claims 56-60 should not be designated as corresponding to Count 2 since (Paper 51 at 3-4):

> Briefly, claims 56-60 of Cabilly do not contain two of the most important features of the claims of the GWI patents, namely, the requirement that the antibody be glycosylated and the requirement that the treatment be applied to humans. These limitations are fundamental to the GWI patents and should be included in the Count.

Glaxo directs us to its preliminary motion 4. We do not consider Glaxo's arguments in its preliminary motion 4 as part of its preliminary motion 5 for reasons stated above.

37 CFR § 1.606 states that a claim that defines the same patentable invention as the count shall be designated as corresponding to the count. In its preliminary motion 5, Glaxo does not sufficiently explain why Cabilly claims 56-60 do not define the same patentable invention as proposed Count 2. As discussed above, Count 2 defines a sub-genus of claim 56 and thus Count 2 would anticipate '611 claim 56. Glaxo has not explained why '611 claims 57-60 would not be anticipated or rendered obvious in view of Count 2. Accordingly, Glaxo has not shown why '611 claims 56-60 should not be designated as corresponding to Count 2.

Glaxo claim designations:

Glaxo states that "[c]laim 1 of the '403 patent, claims 1 and 2 of the '404 patent, and claims 1, 6, 8, and 9 of the '405 patent define the same patentable invention as Count 2 and should correspond to the proposed Count." Glaxo states that its "remaining claims" should not be designated as corresponding to proposed Count 2 "for reasons set forth in GWI Preliminary Motions 6-9."

The Notice Declaring Interference prohibits incorporation by reference (Paper 1 at 9). We have only considered arguments present in preliminary motion 5 in deciding whether the "remaining" Glaxo claims should be designated as corresponding to Count 2. Glaxo has not sufficiently explained why its "remaining" claims should not be designated as corresponding to Count 2 in its preliminary motion 5. Accordingly, the portion of Glaxo preliminary motion 5 seeking to have claim 1 of the '403 patent, claims 1 and 2 of the '404 patent, and claims 1, 6, 8, and 9 of the '405 patent as the only Glaxo claims designated as corresponding to Count 2 is DENIED.

Nonetheless, since we are substituting Count 2 for Count 1, it is appropriate for us to evaluate the Glaxo claims and determine which claims should correspond to Count 2.

In determining whether the disputed claims should be designated as corresponding to Count 2, we look to see whether each disputed claim is the same patentable invention as Count 2. Therefore, we determine whether each disputed claim defines an invention that is anticipated by or would have been obvious in view of proposed Count 2. 37 CFR § 1.601(n).

All the claims of the Glaxo patent were designated as corresponding to Count 1 in the Notice Declaring Interference (Paper 1 at 49). The examiner's attachment to the initial

memorandum gives the examiner's reasoning for proposing that all the Glaxo claims be designated as corresponding to Count 1. The examiner's reasoning would also seem to apply in explaining why all Glaxo's claims should correspond to Count 2.

Count 2 is a subgenus of Count 1. The portion of Count 1 that is not found in Count 2 is that portion of Count 1 relating to the treatment of subjects and the use of antibodies that are not glycosylated by the CHO cells expressing them. None of the Glaxo claims relate to the portion of Count 1 that is not found in Count 2. Thus, under the present circumstances, any Glaxo claim that is anticipated by or would have been obvious in view of Count 1 is also anticipated by or would have been obvious in view of Count 2. Thus, there would seem to be no reason to modify the claims designations from those found in the Notice Declaring Interference (Paper 1 at 49).

Neither party disputes that claim 1 of the '403 patent, claims 1 and 2 of the '404 patent and claims 1, 6, 8, and 9 of the '405 should be designated as corresponding to Count 2 (Paper 51 at 4). Therefore, we will designate these claims as corresponding to Count 2.

Glaxo does dispute that the following claims should be designated as corresponding to Count 2 (Paper 51 at 4). We will refer to these claims as "the disputed claims":

'403 claims 2-7

'404 claims 3-7

'405 claims 2-5 and 7

The disputed claims are summarized below:

'403 claims 3, 5, and 7, '404 claim 6 and '405 claim 5 all relate to methods of treatment using antibodies expressed and glycosylated by CHO cells where the expressed antibodies specifically bind to CDw52 antigen. '405 claim 5 specifies that the cancer being treated is

multiple myeloma. '403 claim 5 specifies that the antibodies used are CDR-grafted. '403 claim 7 specifies that the antibodies used are chimeric.

'403 claims 2, 4, and 6 and '404 claim 7 relate to methods of treatment using antibodies expressed and glycosylated by CHO cells where the expressed antibodies specifically bind to CD4 antigen. '403 claim 4 specifies that the antibodies used are CDR-grafted. '403 claim 6 specifies that the antibodies used are chimeric.

'405 claim 2 relates to a method of treatment for cancer that is non-Hodgkins lymphoma using antibodies expressed and glycosylated by CHO cells.

'405 claims 3 and 4 relate to methods of treatment for cancer that is multiple myeloma using antibodies expressed and glycosylated by CHO cells (claim 3) where the expressed antibodies specifically bind to a T-cell marker (claim 4).

'405 claim 7 relates to methods of treatment for cancer using antibodies expressed and glycosylated by CHO cells where the antibody specifically binds to CD33 or CD38 antigen.

'404 claim 3 is directed to methods of treating autoimmune diseases using antibodies expressed and glycosylated by CHO cells where the autoimmune disease "comprises multiple sclerosis, graft vs. host disease, psoriasis, juvenile onset diabetes, Sjogrens' disease, thyroid disease, myasthenia gravis, transplant rejection or asthma."

'404 claim 4 relates to methods of treating a T-cell mediated disorder using antibodies expressed and glycosylated by CHO cells where the T-cell mediated disorder "comprises severe vasculitis, rheumatoid arthritis or systemic lupus."

'404 claim 5 depends on '404 claim 4 and specifies that the T-cell mediated disorder is rheumatoid arthritis.

It does not appear to be disputed that altered CDR-grafted and chimeric antibodies against T-cell antigens such as CDw52 and CD4 and cancer cell antigens such as CD33 and CD38 were known in the art at the time the Glaxo applications were filed (e.g., '404 at 3:51-61). For example, Glaxo states in its '404 patent that the CDw52 antibody CAMPATH-1H[13] was known and described in EP 0 328 404[14] ("EP '404) ('404 at 3:59-67). EP '404 discloses the use of CAMPATH-1H for the treatment of cancer, in particular non-Hodgkins lymphoma in leukaemic phase (EP '404 at 11), and for immunosuppression purposes (EP '404 at 4). EP '404 discloses that antibodies for treating particular conditions associated with transplant rejection, e.g., graft-vs. host disease, were known ('404 at 4).

Moreover, the form of the Glaxo claims indicate that Glaxo considers its invention to lie in the expression and glycosylation of known antibodies in CHO cells and not in the selection of a condition to be treated and an antibody effective in treating the condition. In particular, the condition to be treated and the antibody effective in treating the condition are part of the preamble of Glaxo's claims that appear to be drafted in accordance with 37 CFR § 1.71(e) (i.e., the Glaxo claims are presented as Jepson claims). The preamble of a Jepson claim is impliedly admitted to be prior art . 37 CFR § 1.71(e)(1) and Sjolund v. Musland, 847 F.2d 1573, 1577, 6 USPQ2d 2020, 2023 (Fed. Cir. 1988).

Count 2 includes a method of treating cancer and T-cell mediated disorders using chimeric and CDR-grafted antibodies that are expressed and glycosylated in CHO cells (FF 27).

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[13] CAMPATH is said to be a trademark of the Wellcome Foundation Ltd. ('403 at 3:66-67)

[14] EP 0 328 404 A1 (copy attached) is said to have been published on 16 August 1989.

Taking Count 2 as prior art, in combination with the knowledge of one skilled in the art at the time the Glaxo applications were filed, (e.g., the known use of chimeric and CDR-grafted antibodies against T-cell antigens such as CDw52 and CD4 and cancer cell antigens such as CD33 and CD38), one skilled in the art would have been motivated to express and glycosylate the known antibodies in CHO cells. Knowing that it is possible and useful to express and glycosylate antibodies in CHO cells, on the record before us,[15] one having ordinary skill in the art would have been motivated to use the CHO cells to express and glycosylate the antibodies specifically claimed by Glaxo.

Each of the disputed claims is directed to a species or a subgenus of the antibodies or conditions to be treated found in Count 2. The fact that the species or subgenus of the disputed claims is encompassed by Count 2, does not, by itself, establish a *prima facie* case that the claims would have been obvious in view of Count 2. In re Baird , 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). However, the situation before us differs from the situation presented in Baird. In particular, in Baird there was no secondary reference directing one to the specific compound claimed by applicant. In the circumstances before us, the prior art recognized the particular antibodies and conditions to be treated at the time of the Glaxo filings. When we combine the teachings of Count 2 with the direction provided by the prior art, we conclude that one having ordinary skill in the art would have been motivated to select the particular antibodies and conditions to be treated found in the Glaxo disputed claims.

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[15] Glaxo preliminary motions 6-9 are dismissed infra at 51. We have not considered the arguments presented in Glaxo preliminary motions 6-9 as part of Glaxo preliminary motion 5 for reasons for reasons stated supra at 27.

While we have not considered the arguments presented in Glaxo preliminary motions 6-9 (infra at 51 and supra at 27), we note Glaxo's position that claim 2 of its '405 patent (directed to the treatment of non-Hodgkins lymphoma) would have been unobvious in view of Count 1 based on the secondary consideration of commercial success. In particular, Glaxo argues that the commercial success of Rituxan[16] establishes that '405 claim 2 would have been unobvious (Paper 52 at 15). Evidence of commercial success must be commensurate with the scope of the claim it is offered to support. In re Tiffin, 448 F.2d 791, 792, 171 USPQ 294, 294 (CCPA 1971). We determine that Glaxo has not adequately shown commercial success for the subject matter of '405 claim 2 for at least the reason that '405 claim 2 is not limited to Rituxan.

Thus, we will designate all the Glaxo claims as corresponding to Count 2.

Cabilly's priority benefit (Cabilly preliminary motions 12 and 13)

Cabilly was accorded priority benefit of the '419 and '457 applications as to the subject matter of Count 1 in the Notice Declaring Interference (FF 13). In its preliminary motion 5, Glaxo seeks to deny Cabilly priority benefit of the '419 and '457 applications for Count 2.

In its preliminary motions 12 and 13, Cabilly has moved to deny Cabilly priority benefit of its '419 and '457 application for Count 2. Thus Glaxo preliminary motion 5 is seeking the same relief as Glaxo preliminary motions 12 and 13.

The types of preliminary motions that may be filed in an interference are set forth at 37 CFR § 1.633. 37 CFR § 1.633(g) allows a moving party to attack priority benefit accorded to another party in the Notice Declaring Interference. However, 37 CFR § 1.633 does not allow for

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[16] Rituxan is said to be sold by Genentech under the trade name of Rituximab and is said to recognize CD 20 antigen and treat non-Hodgkins lymphoma (Paper 52 at 15-16).

a distinct preliminary motion attacking priority benefit where none has been granted in the Notice Declaring Interference, e.g., for a proposed count. Instead, 37 CFR § 1.637(c)(1)(vii) directs a party seeking to substitute a count to explain why an opposing party should not be accorded the same priority benefit it was accorded in the Notice Declaring Interference for the proposed count.

Glaxo preliminary motions 12 and 13 are not provided for under 37 CFR § 1.633 and are unnecessary since Glaxo explains why it believes that Cabilly should not be accorded priority benefit of the '419 and '457 applications in its preliminary motion 5. It is inappropriate for Glaxo to present further arguments in its preliminary motions 12 and 13 in an attempt to avoid the page number limitations applicable to Glaxo preliminary motion 5. We have not considered arguments presented in Glaxo preliminary motions 12 and 13 only to the extent those arguments are also presented in Glaxo preliminary motion 5. Glaxo preliminary motion 12 and 13 are DISMISSED as improper.

Cabilly's benefit for Count 2 and Glaxo preliminary motion 3

Below we address together Cabilly preliminary motion 3 and Glaxo's arguments why Cabilly should not be accorded priority benefit of its '419 application for purposes of Count 2.

Since we determine, for reasons stated below, that Glaxo has not shown that Cabilly should not be accorded priority benefit for its '419 application as to Count 2, we need not and have not decided whether Cabilly is entitled to priority benefit of its '457 application for the subject matter of Count 2. Thus that portion of preliminary motion 5 seeking to deny Cabilly priority benefit of the '457 application is DISMISSED as moot.

In particular, we note that Glaxo's preliminary statement does not allege a date sufficient to overcome the '419 filing date. (FFs 14, 15). While in some situations it may be appropriate to

allow a party to modify its preliminary statement when the count is modified, in the present situation the filing of a modified preliminary statement by Glaxo is not necessary. Since the subject matter of Count 2 is encompassed by the subject matter of Count 1, we see no reason why Glaxo's alleged dates would be any earlier for the subject matter of Count 2 than they are for the subject matter of Count 1.

In Glaxo preliminary motion 5, Glaxo argues that Cabilly should not be accorded priority benefit of the '419 application, filed 10 June 1988, for the subject matter of Count 2. In particular, Cabilly argues that the '419 application does not provide written description as required by 35 USC § 112, ¶ 1, for an embodiment within the scope of Count 2. In Glaxo preliminary motion 3, Glaxo moves under 37 CFR § 1.633(a) for judgment that the involved Cabilly claims are unpatentable for failure to comply with the written description requirement of 35 USC § 112, ¶ 1.

Glaxo acknowledges that Cabilly's involved application and the '419 application are "identical" (Paper 203 at 14) and that Glaxo's arguments in its preliminary motion 3 are substantially the same as its arguments that the '419 application fails to provide written description for an embodiment of the Count[17] (Paper 203 at 15).

The written description required for patentability differs from that required for priority. Priority is not a basis for granting a patent to a party; rather, it is the basis for denying patentability to another party under 35 U.S.C. 102(g)(1). Cromlish v. D.Y., 57 USPQ2d 1318, 1319 (BPAI (ITS) 2000). Thus, a single described and enabled embodiment within the scope of

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[17] While counsel for Glaxo appeared to be referring to Count 1, we note that Glaxo's arguments that the '419 application lacks written description for an embodiment within the scope of the count appear to be substantially the same whether the count is Count 1 or Count 2.

the count is sufficient for priority benefit. Hunt v. Treppschuh, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975). Count 2 includes '611 claims 53 and 55. If Glaxo has failed to show that '611 claims 53 and 55 are unpatentable based on a lack of written description, then Glaxo has also failed to show that Cabilly's '419 application lacks written description for even a single embodiment within the scope of Count 2.

Whether the specification contains a written description of the claimed invention is a factual inquiry. Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). The applicants' specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicants were in possession of the invention. Vas - Cath Inc. v. Mahurkar , 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." In re Gosteli , 872 F.2d at 1012, 10 USPQ2d at 1618.

Glaxo does not argue that the '419 application fails to provide an enabling disclosure for an embodiment within the scope of Count 2 (FF 35).[18]

According to Glaxo, its arguments are supported by the testimony of Dr. Youle and Dr. Vitetta. The difficulty we have with Glaxo's position in its preliminary motions 3 and 5, is that Glaxo has failed to direct us to any specific portions of Dr. Youle's or Dr. Vitetta's testimony (FF 43 and 51) . Therefore, we are left to speculate as to what portions of the testimony Glaxo is relying upon to support its arguments. It is not our role to scour the testimony

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[18] Glaxo does argue that Cabilly's '611 application fails to provide an enabling disclosure in Glaxo preliminary motion 10. Glaxo preliminary motion 10 is denied for reasons set forth below.

of Dr. Youle and Dr. Vitetta to make out Glaxo's case for it nor would it be fair to Cabilly for us to do so. Leveen v. Edwards, 57 USPQ2d at 1413 (BPAI (ITS) 2000) ("[t]he board will not engage in "role-shifting" by becoming counsel for a party and turning the interference into a contested case between (1) the party and the board, on the one hand, versus (2) the opponent, on the other hand").

We also note that the subject matter of the interference is technically complex making it especially important that each party point to specific portions of the evidence that support its arguments. While Glaxo points to some particular portions of the testimony of Dr. Youle in its reply 3, for example, (FFs 44, 52), it is not appropriate for Glaxo to make out its *prima facie* case in its reply.[19] Glaxo has not directed us to specific evidence sufficient to support Glaxo's arguments that Cabilly's '611 claims are unpatentable for lack of written description and Glaxo's arguments that Cabilly should not be accorded priority benefit of its '419 application. We do not consider the unsupported attorney arguments made in Glaxo preliminary motions 3 and 5 as evidence in the interference. See Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 595, 44 USPQ2d 1609, 1615 (Fed. Cir. 1997). Accordingly, Glaxo has not set forth a *prima facie* case.

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[19] ¶ 31 of the Notice Declaring Interference states that (Paper 1 at 27-28):

> As provided by the rules, no new issues are to be raised in replies.
>
> A new issue will be deemed to be raised in a reply if the reply refers to new evidence which is necessary to make out a prima facie case for the relief requested in, and/or which could have been included with, the motion.
>
> A reply which is longer than a motion or an opposition probably raises new issues.
>
> If a reply raises any new issue or belatedly relies upon evidence which should have been earlier presented, **the entire reply and belatedly relied upon evidence will not be considered**. The board will not attempt to sort out legitimate reply from improper reply.

Therefore, we deny Glaxo preliminary motion 3 and that portion of Glaxo preliminary motion 5 seeking to deny Cabilly priority benefit of its '419 application for Count 2.

Even when we consider the Glaxo arguments in view of the testimony of Dr. Youle and Dr. Vitetta, we still determine that Glaxo has failed to set forth a *prima facie* case and deny Glaxo preliminary motion 3 and that portion of preliminary motion 5 attacking Cabilly's priority benefit of the '419 application for proposed Count 2. We address the particular arguments set forth in Glaxo preliminary motions 3 and 5 below in view of our understanding of the testimony of Dr. Youle and Dr. Vitetta.

1. Glycosylation

Glaxo argues that the involved applications do not describe antibodies that are glycosylated and, in particular, antibodies that are glycosylated by CHO cells (Paper 49 at 21). Glaxo argues that the Cabilly applications do not describe antibodies glycosylated by CHO cells since "[i]t is possible that an antibody expressed by a CHO cell might not be glycosylated." Glaxo points to the declaration of Dr. Youle (Exh. 2012) in support of its position. According to Glaxo, "Dr. Youle suggests several different scenarios whereby antibodies produced by CHO cells might not be glycosylated" (Paper 49 at 21-22).

The only specific mention of CHO cells found in the Cabilly applications is as follows (FF 42):

> Examples of such useful host cells [for expressing antibodies] are VERO and HeLa cells, Chinese hamster ovary (CHO) cell lines, and WI38, BHK, COS-7 and MDCK cell lines.

Glaxo argues that "[t]he present situation is strikingly similar to that present in In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)". Glaxo also points to Fujikawa v.

Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir 1996) for support of its position that the Cabilly applications did not provide the appropriate "blaze marks" to direct one to the claimed subject matter or even to an embodiment within the scope of Count 2 (Paper 49 at 14-17 and Paper 51 at 22-23).

In both Ruschig and Fujikawa, written description was found to be lacking for compounds that were not specifically disclosed even though the compounds could be arrived at by making selections within the genus of compounds disclosed. The situations presented in Ruschig and Fujikawa appear to be significantly different than the situation before us. For example, in Ruschig, the applicant described a very broad genus of compounds but provided no specific disclosure of the compound claimed. In Fujikawa, a party sought to add a count to a narrow sub-genus of compounds. The narrower sub-genus could be arrived at only by picking and choosing particular moieties at various positions within those disclosed. The Fujikawa decision noted that the disclosure did not provide blaze marks as to what subject matter was of particular interest. Fujikawa, 93 F.3d at 1905, 39 USPQ2d at 1571. In contrast, the Cabilly applications specifically disclose that within multicellular organisms hosts, interest has been "greatest in vertebrate cells". (Exh. 2103 at 18:1-10). Cabilly describes CHO cell lines as "useful host [vertebrate] cell lines" for antibody expression in vertebrate cells (FF 42). Only seven other vertebrate cell lines are specifically disclosed. Thus, Glaxo has not shown that the Cabilly applications did not provide adequate blaze marks to direct one to use CHO cells as hosts for antibody expression. Furthermore, the Cabilly applications recognize that a mammalian cell would be expected to glycosylate an antibody it expresses (FF 41).

Dr. Youle's testimony:

In its preliminary motions 3 and 5, Glaxo does not point us to any particular portion of Dr. Youle's testimony. Accordingly, as noted above, we do not find Glaxo's arguments that rely upon Dr. Youle's testimony to be persuasive. At any rate, when we review Dr. Youle's testimony, we do not find that it shows that the Cabilly applications fail to provide written description for antibodies that are glycosylated by CHO cells.

At the outset we wish to note that it is not clear to us from Glaxo's arguments if it is Glaxo's position that a CHO cell would not be expected to glycosylate an antibody it expresses. For example, on the one hand, Glaxo states that "[a]s clearly documented in Youle Declaration 1 [Exhibit 2012], glycosylation of antibodies by CHO cells is not inherent" (Paper 51 at 14). On the other hand, Glaxo states that "[it] is possible to control and inhibit the glycosylation of an antibody expressed by a CHO cell" (Paper 49 at 11-12), "even if a CHO cell usually inherently expresses a glycosylated antibody, the glycosylation could be removed before attempting to use the antibody for treatment", and that "GWI does not dispute that the antibody of Cabilly's claims 56-60 could have been glycosylated, [since] [t]he claims recite an antibody expressed by CHO cells" (Paper 156 at 5- 6). Dr. Youle's testimony does not help us clarify Glaxo's position.

Dr. Youle testified that, in view of Cabilly's statement that glycosylation can be "undesirable", he "would be reluctant to attempt to use eukaryotic organisms [such as CHO cells] to express recombinant antibodies in order to avoid possible undesirable effects of glycosylation on antibody production" (FF 45). Moreover, Dr. Youle testified that, in CHO cells expressing antibodies, it would have been possible to take steps to either inhibit glycosylation or to remove the sugar groups after glycosylation (FF 45). Thus, a portion of Dr. Youle's testimony

indicates that mammalian cells, such as CHO cells, would be expected to express antibodies in glycosylated form, barring any intervention to inhibit glycosylation.

On the other hand, Dr. Youle testified that in mammalian cells, "the addition of a special 'leader sequence' would be required to steer the protein to the secretory pathway" that would be necessary "for any hope of proper glycosylation of the antibodies." According to Dr. Youle, the Cabilly application does not teach the addition of such a leader sequence (FF 45). Thus, a portion of Dr. Youle's testimony indicates that, absent an appropriate leader sequence, CHO cells would not be expected to express antibodies having "proper glycosylation."

Glaxo does not argue in its preliminary motions 3 and 5 that the Cabilly applications do not teach a leader sequence required for "proper glycosylation". In its preliminary motions 3 and 5, Glaxo offers no sufficient explanation of the significance of Dr. Youle's testimony regarding the need for a leader sequence. Without further explanation of what Dr. Youle means by "proper glycosylation" and "special leader sequence", we are left to speculate as to the significance of this portion of Dr. Youle's testimony. We will not speculate on the testimony's significance for at least the reason that it would be unfair to Cabilly for us to do so.

We note that regarding "proper glycosylation", Glaxo states that (Paper 51 at 11):

> Thus, to achieve proper glycosylation and produce antibodies that are therapeutically effective in humans and have proper effector functions, the recombinant antibodies should be produced in a cell system which glycosylates the antibodies with a glycosylation pattern that is very similar to the glycosylation pattern in a human B-cell (the cell type which produces antibodies in vivo).

Glaxo does not explain why the CHO cells system described by Cabilly would not allow for "proper glycosylation". We further note that Cabilly teaches expression vectors for use in

mammalian cells ('567 at 10:39-53). Glaxo has not explained why these expressions vectors would not allow for "proper glycosylation" of the antibodies expressed.

As noted above, Dr. Youle testified that in CHO cells expressing antibodies, it would have been possible to take steps to either inhibit glycosylation or to remove the sugar groups after glycosylation (FF 45) .

Glaxo has not directed us to any portion of the Cabilly applications that directs one to take the steps referred to in Dr. Youle's testimony to inhibit glycosylation. We note that in the section of the Cabilly applications entitled "BACKGROUND OF THE INVENTION", it is stated that antibodies in glycosylated form may "under some circumstances" be undesirable (FF 41) and that "[t]he antibodies of the present invention do not suffer from the foregoing drawbacks." While the Cabilly applications describe antibodies that are not glycosylated (e.g., those produced in *E. coli*), we do not read this section of the Cabilly applications as limiting the antibodies of the invention to those that are not glycosylated. In particular, the section notes that glycosylated antibodies are undesirable only "under some circumstances." Since the Cabilly applications include antibodies that are not glycosylated, one could select a non glycosylated antibody when a glycosylated antibody is undesirable and thus avoid the "drawback" of "inevitable" glycosylation.

Dr. Vitetta 's testimony:

Glaxo does not appear to rely upon Dr. Vitetta's testimony to support its arguments regarding glycosylation. Dr. Vitetta's testimony is consistent with Dr. Youle's to the extent that Dr. Vitetta's testimony indicates that the one would not select CHO cells for antibody expression

if glycosylation was not desired since "eukaryotic expression cells usually glycosylate proteins in some way" (Exh. 2028 at ¶ 17).

The EPO application:

Glaxo states that "[i]t is also interesting to note that the claims in Cabilly's corresponding European Patent [Exhibit 2057] were eventually restricted to non-glycosylated antibodies" (Paper 49 at 23). Glaxo has not sufficiently explained to us how the record before the European Patent Office (EPO) and the present record are alike. Therefore, we cannot determine that the situation presented to the EPO is the same as the present situation. For example, we do not know if the EPO based its decision (see Exh. 2047) on prior art that is not before us. At any rate, despite any similarities between the situation before the EPO and the present one, we are not bound by the decision of the EPO.

2. *The original claims and examples:*

Glaxo argues that the Cabilly applications[20] do not describe subject matter within the scope of proposed Count 2 as part of its invention. Glaxo points to portions of the introduction, portions of the summary of the invention, and the examples within the Cabilly applications. Glaxo points out that the involved Cabilly claims were not part of the original disclosure of the '419 application.

In support of its arguments, Glaxo points to the testimony of Dr. Youle (Exh. 2012) and Dr. Vitetta (Exh. 2028). According to Glaxo, Dr. Youle and Dr. Vitetta reach similar

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[20] In its preliminary motions 3 and 5, Glaxo at times directs us to Exhibit 2006 (the '457 application) as the "Cabilly application". We have looked instead to Exhibit 2102 (the '419 application) or the 2103 (the '611 application) as appropriate, since it is apparent to us that is what Glaxo intended.

conclusions regarding the Cabilly invention, in particular, that "the Cabilly invention is directed to cloning of the DNA encoding an anti-CEA antibody and preparation of the antibody by recombinant techniques in *E. Coli*" (Paper 49 at 9).

Glaxo does not direct us to any particular portion of Dr. Youle's testimony nor to any particular portion of Dr. Vitetta's testimony (at Exh. 2028). The portions of Dr. Youle's and Dr. Vitetta's testimony referred to by Glaxo appear to be at Exh. 2012, ¶ 5 and Exh. 2921, ¶ 12, respectively.

Cabilly concedes that it did not present claims to a therapeutic method during the prosecution of its '419 application (Paper 104 at 3). However, as acknowledged by Glaxo, it is appropriate for a party to add claims to other embodiments supported by the disclosure during prosecution of its application (Paper 154 at 5). While it is possible that Cabilly did not originally intend to claim the subject matter of the '611 claims, the relevant inquiry is whether Cabilly described the claimed subject matter sufficiently to be entitled to claim it without violating the written description requirement of 35 USC § 112, ¶ 1.

Glaxo argues that the therapeutic method claims using glycosylated CHO cells were not presented until after the Cabilly attorneys read the Glaxo patents. However, it is not improper to amend or insert claims intended to cover a competitor's method that the applicant's attorney has learned about during the prosecution of a patent application. Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874, 9 USPQ2d 1384, 1390 (Fed. Cir. 1988).

While Glaxo directs us to the opinion in Gentry Gallery Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 USPQ2d 1498, 1503, the situation in Gentry is different from the situation before us. We note the following portion of Gentry (emphasis added):

> Finally, **although not dispositive, because one can add claims to a pending application directed to adequately described subject matter**, Sproule [the Gentry inventor] admitted at trial that he did not consider placing the controls outside the console until he became aware that some of Gentry's competitors were so locating the recliner controls. Accordingly, when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console.

The decision in Gentry states that an applicant may add claims to a pending application so long as the subject matter of the added claims is adequately described. We note that while the testimony of the Gentry inventor indicating that he had not originally considered including the added feature was considered by the Court, the testimony alone was not found "dispositive". At any rate, Glaxo has not directed us to testimony from a Cabilly inventor that would indicate that the inventor did not originally intend to include the subject matter of the '611 claims or Count 2 in the Cabilly applications.

Glaxo argues that none of the working examples presented in the Cabilly applications are directed to the subject matter of the '611 claims or Count 2 (Paper 51 at 19). However, Glaxo has not directed us to adequate authority to support the proposition that an application must contain a working example to comply with the written description requirement of 35 USC § 112, ¶ 1.[21]

3. Therapeutic treatment

Glaxo argues that the Cabilly applications do not describe a method of treating a human suffering from a disease. In particular, Glaxo argues that the portion of the Cabilly applications that discusses therapeutic treatment is referring to the prior art (Paper 49 at 12-14).

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[21] The lack of a working example is a factor to be considered in determining compliance with the enablement requirement of 35 USC § 112, ¶ 1, In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988),

In particular, the following portion ("first portion") of the Cabilly applications appears under the heading "Background of the Invention" (FF 48):

> In another important use, antibodies can be directly injected into subjects suffering from an attack by a substance or organism containing the antigen in question to combat this attack. This process is currently in its experimental stages, but its potential is clearly seen. Third, whole body diagnosis and treatment is made possible because injected antibodies are directed to specific target disease tissues, and thus can be used either to determine the presence of the disease by carrying with them a suitable label, or to attack the diseased tissue by carrying a suitable drug.

In a portion ("second portion") of the application that appears under the heading "Detailed Description", the Cabilly applications state that chimeric antibodies having human constant regions are "less likely to elicit an immune response from a human subject when the antibodies are injected than would the constant region from a non-human source" (FF 49).

Glaxo has not shown that the Cabilly applications do not describe therapeutic treatment. We read this first portion of the Cabilly specification, found under the heading "Background of the Invention", as describing direct injection as a way of using antibodies in general in therapeutic treatment. Glaxo has not sufficiently explained why one skilled in the art would not read this first portion of the Cabilly applications as describing a use for the antibodies the applications describe. Moreover, the second portion of the Cabilly applications that appears under the heading "Detailed Description" describes injecting antibodies into a human subject. When we consider the two portions of the Cabilly applications together, we determine that Glaxo has not shown that the Cabilly applications do not reasonably convey to one skilled in the art that Cabilly was in possession of the therapeutic treatment of humans.

Glaxo argues that "there is no statement that Cabilly intended [the treatment of tumors with anti-CEA$^{+[22]}$ antibody] as part of his invention" (Paper 49 at 12, bracketed material added). Glaxo's argument is relevant only to its preliminary motion 3 since Count 2 does not require the treatment of a human tumor having using anti-CEA antibody.

Cabilly claims 54 and 57-60, which are not part of Count 2, include the treatment of a human tumor using an anti-CEA antibody. Glaxo does not adequately explain why Cabilly's description of anti-CEA antibodies and the use of anti-CEA antibodies for treating tumors (Exh. 2103 at Ex. E.1-E.10, Ex. E.4, and Ex.E.5 at 49-52) in combination with Cabilly's description of therapeutic treatment using antibodies is insufficient to convey that Cabilly was in possession of a method of therapeutic treatment using anti-CEA antibodies. For example, Cabilly teaches that anti-CEA antibodies "have the potential for use in treatment of those human tumors which appear to support CEA at their surfaces" (Exh. 2102 at Ex. E.1) . Cabilly also provides an example of a method of making a chimeric antibody comprising a human constant region and a murine anti-CEA variable region (Exh. 2102 at Ex. E.4). While the chimeric antibody exemplified is expressed in *E.coli*, Cabilly discloses that the antibodies of the invention may be expressed in CHO cells (Exh. 2102 at 18:8-10) When we consider the '611 application as a whole, we determine that Glaxo has not shown that the '611 application fails to reasonably convey to one skilled in the art that Cabilly was in possession of therapeutic treatment of humans using anti-CEA antibodies expressed by CHO cells.

Glaxo points out that the Cabilly applications describe the use of antibodies to treat human diseases and disorders by direct injection as "experimental" and as having "potential"

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[22] We understand CEA to be carcinoembryonic antigen.

(Paper 49 at 13-14). However, Glaxo has not provided sufficient reasoning and has directed us to no authority supporting the proposition that a product that is the subject of ongoing experiments cannot be adequately described under 35 USC § 112, ¶ 1.

Moreover, other types of therapeutic treatment are described by Cabilly and are not described as "experimental". For example, the Cabilly applications describe the injection of antibodies targeted for diseased cells and carrying a suitable drug (FF 48).

Glaxo argues that Cabilly "does not disclose any pharmaceutical formulation or dosage regimen" (Paper 49 at 21). Glaxo has not sufficiently explained why the description of a particular formulation or dosage regimen is necessary for written description since no formulation or dosage regimen is required by the Cabilly claims.

Summary:

Glaxo has the burden of showing that the Cabilly applications do not meet the written description requirement. 37 CFR § 1.637(a). We determine that Glaxo has not met its burden.

While the Cabilly applications do not provide as clear and as detailed a written description as they might have, to meet the written description requirement of 35 USC § 112, ¶ 1, the applications need only convey with reasonable clarity to those skilled in the art that Cabilly was in possession of the invention. Vas - Cath Inc. v. Mahurkar , 935 F.2d at 1563, 19 USPQ2d at 1117.

Glaxo preliminary motion 3 is DENIED. The portion of Glaxo preliminary motion 5 seeking to deny Cabilly priority benefit of its '419 application for the subject matter of Count 2, is DENIED. Since Glaxo did not set forth a *prima facie* case, we need not and have not

considered Cabilly opposition 3 and that portion of Cabilly opposition 5 addressing Glaxo's argument seeking to deny Cabilly priority benefit of the '419 application.

Glaxo preliminary motion 14

In its preliminary motion 14, Glaxo moves for priority benefit of the filing dates of the following Glaxo applications for its proposed Count 2: (1) 08/046,893, filed 15 April 1993, (2) 07/943,146, filed 10 September 1992, and, (3) 07/777,730, filed 16 October 1991. Glaxo was accorded priority benefit of the applications for Count 1 (FF 12).

Cabilly opposes, arguing that the applications do not describe an enabled embodiment within the scope of Count 2. Since Glaxo cannot prevail on priority even if its preliminary motion 14 is granted, we need not and have not decided Glaxo preliminary motion 14. Glaxo preliminary motion 14 is DISMISSED as moot.

Glaxo preliminary motion 11

In its preliminary motion 11, Glaxo moves for judgment that there is no interference-in-fact between its claims and the '611 Cabilly claims.

An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention. 37 CFR § 1.601(j). Glaxo does not argue that no corresponding Glaxo and no corresponding Cabilly claim define the same patentable invention as defined by 37 CFR § 1.601(n). Instead, Glaxo argues that Cabilly's claims are unpatentable under 35 USC § 112, ¶ 1, and thus do not define a "patentable invention". However, patentability to a particular party is not required by 37 CFR § 1.601(j) or 1.601(n). Rather "patentability" under §§ 102 and 103 is judged by comparing one party's claims to the others

assuming one party's claims to be prior art to the opponent's claims. Since Glaxo has not sufficiently explained why there is not an interference -in-fact under 37 CFR § 1.601(j), Glaxo has not met its burden of proof. 37 CFR § 1.637(a).

Glaxo provides four other reasons why its motion should be granted:

(1) The '611 claims are not prior art against Glaxo since they were not added to the '611 application until 14 years after Cabilly's earliest benefit filing date.

(2) Glaxo established the patentability of its claims over a patent that issued from a Cabilly benefit application during ex parte prosecution before the examiner.

(3) The Glaxo applications are patentable over any claims that the '611 application can support as required by 35 USC § 112.

(4) The '611 claims should not have been allowed and thus there is no interference between a "patentable" '611 claim and a Glaxo claim.

Most of the arguments in Glaxo preliminary motion 11 are found in Glaxo preliminary motions discussed above and therefore are addressed elsewhere in this decision. Nonetheless, in response to each of the four reasons, we again note the following:

(1) For purposes of priority benefit, we look to the specification of earlier filed application (not just the claims) to determine if an embodiment within the scope of the Count is present. Such an embodiment is what is prior art against the opposing party. Cromlish v. D.Y., 57 USPQ2d at 1319 and 35 USC § 102(g). Moreover, 37 CFR § 1.601(n) assumes a first invention is prior art to another invention in defining whether the other invention is the "same patentable invention" as the first invention and vice versa.

(2) Neither we, nor Cabilly, are bound by an ex parte decision of the examiner of the Glaxo applications. Glaxo Wellcome, Inc. v. Cabilly, 56 USPQ2d 1983, 1984 (BPAI (ITS) 2000). Moreover, it does not appear, based on the evidence pointed out to us, that the issue of whether the '611 claims interfere-in-fact with the Glaxo claims was before the examiner.

(3) and (4) Glaxo has not shown that the '611 application lacks the required written descriptive support. See pages 31 to 45 of this opinion.

Glaxo preliminary motion 11 is DENIED. Since Glaxo did not set forth a *prima facie* showing, we need not and have not considered Cabilly opposition 11.

Glaxo preliminary motion 10

In its preliminary motion 10, Glaxo moves for judgment that the '611 involved claims are unpatentable under 35 USC § 112, ¶ 1, as lacking an enabling disclosure. In particular, Glaxo states that (Paper 56 at 1):

> This Motion is based on the allegation that the claims are not enabled as of the "effective filing date" of the Cabilly application, which according to the USPTO is April 8, 1983.

"Enablement, or utility, is determined as of the application filing date." In re Brana, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995), Cf. Reiffen v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (written description is determined as of the application filing date and not the filing date of parent applications). The problem with Glaxo preliminary motion 10 is that it does not address the proper inquiry, i.e., were the claims of the '611 application enabled as of the filing date of the '611 application (i.e., 12 August 1997)? Instead, Glaxo preliminary motion 10 focuses on the state of the art as of the filing date of the '457 application, a grandparent application of the '611 application. For

example, Glaxo states that "[t]he state of the art of both expression of recombinant antibodies and therapeutic use of antibodies was in its infancy in 1983" (Paper 56 at 18).

Glaxo states that "[r]ecombinant antibodies expressed in a CHO cell expression system" were not known until 1987[23] (Paper 56 at 3). Dr. Vitetta testified that one skilled in the art "would not have been enabled to practice the invention which is recited in Claims 53-60 in 1983" (Exh. 2018 at ¶ 20) and that "it would have required undue experimentation (4 years) to express a glycosylated recombinant antibody in CHO cells based on the disclosure of Cabilly and the available technology in 1983." (Exh. 2028 at ¶ 25).

Dr. Youle's testimony is consistent with Dr. Vitetta's as to the state of the art in 1983 (Exh. 2012 at ¶ 19). In addition Dr. Youle stated that as of the filing date of the '419 application, he believes "that separate inventive effort would have been required to make recombinant antibodies in CHO cells and determine if they were therapeutically active" (Exh. 2012 at ¶ 20).

Neither Glaxo's arguments nor Dr. Youle's and Dr. Vitetta's testimony address the state

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[23] When asked about Cabilly's enablement at oral hearing, Glaxo counsel Gerald Murphy answered:

> Well, the prior art developed between '83 and '88. I would like to really emphasize that Glaxo, really its main attack on Cabilly is written description (Paper 203 at 57);.
>
> I'm not prepared to state when they [Cabilly] were enabled. I know we've attacked the '83 enablement filing date (Paper 203 at 16-17);
>
> and
>
> There was some technology developed between '83 or '86 or '87, the second Cabilly filing date. So the enablement issues with respect to '83 and '87 are different because the technology developed (Paper 203 at 17).

of the art as of the filing date of the '611 application. Thus, Glaxo has not met its burden by showing that the '611 claims were not enabled as of the filing date of the '611 application.

At one point in Glaxo preliminary motion 10, Glaxo argues that a 1988 article disclosing CHO cell expressed antibodies did not disclose *in vivo* therapeutic activity of the antibodies (Paper 56 at 19). To the extent Glaxo is arguing that the '611 claimed subject matter was not enabled in 1988, such argument still does not address whether the '611 claimed subject matter was enabled as of the filing date of the '611 application.

Cabilly's entitlement to benefit under 35 USC § 120 for the 1983 filing date of the '457 or the 1988 filing date of the '419 application might be relevant if Glaxo had moved under 37 CFR 1.633(a) for judgment that the '611 claims are unpatentable over prior art dated after the '457 or '419 filing date. However, Glaxo did not so move.

Glaxo preliminary motion 10 seems to be directed more at attacking the priority benefit accorded to Cabilly for the 1983 filing date of the '457 application. Glaxo filed preliminary motion 1 attacking the priority benefit accorded to Cabilly for the '457 application and that motion is dismissed as moot.

Glaxo's arguments that Cabilly should not be accorded priority benefit of its '419 application are based on Glaxo's position that the '419 application lacks written description for an embodiment within the scope of Count 2. Glaxo does not argue that the '419 application lacks enablement for an embodiment within the scope of proposed Count 2 (FF 35).

Glaxo does not show that the '611 claims were not enabled as of the 12 August 1997 filing date of the '611 application. Glaxo preliminary motion 10 is DENIED. Since Glaxo did

not meet its burden by making a *prima facie* showing, we need not and have not considered Cabilly opposition 10.

Glaxo preliminary motions 1 and 2

Glaxo preliminary motion 1 attacks the priority benefit accorded to Cabilly for the filing date of the '457 application for the subject matter of Count 1. Glaxo preliminary motion 2 attacks the priority benefit accorded to Cabilly for the filing date of the '419 application for the subject matter of Count 1.

Since we grant Glaxo's preliminary motion 5 to the extent it seeks to substitute proposed Count 2 for Count 1, Glaxo preliminary motions 1 and 2 are DISMISSED as moot.

Glaxo preliminary motion 4

In its preliminary motion 4, Glaxo moves to have Cabilly claims 56-60 designated as not corresponding to Count 1. Since we grant Cabilly preliminary motion 5 to substitute proposed Count 2 for Count 1, Glaxo preliminary motion 4 is DISMISSED as moot.

Glaxo preliminary motions 6-9

In Glaxo preliminary motions 6-9, Glaxo moves to have certain of its involved claims designated as not corresponding to Count 1. We grant Glaxo preliminary motion 5 to substitute proposed Count 2 for Count 1. Thus, Glaxo preliminary motions 6-9 are DISMISSED as moot.

C. Other Glaxo motions

Glaxo miscellaneous motion 10

Glaxo miscellaneous motion 10 is treated as a motion to suppress evidence (FF 23). Glaxo moves to suppress Cabilly Exhibits 1090-1091, 1093-1094, 1095, 1095A, 1095B, 1112, 1113, and 1114 (Paper 176 at 2). We have not relied upon Cabilly Exhibit 1090-

1091, 1093-1094, 1095, 1095A, 1095B, 1112, 1113, and 1114 as a basis for our decision. Accordingly, we need not and have not decided Glaxo miscellaneous motion 10. Glaxo miscellaneous motion 10 is DISMISSED as moot.

Glaxo miscellaneous motion 11

Glaxo miscellaneous motion 11 is treated as a motion to suppress evidence (FF 23). Glaxo moves to suppress specific portions of Cabilly Exhibits 1100, 1120, 1121, and 1124 (Paper 177 at 2). We have not relied upon the portions of Cabilly Exhibits 1100, 1120, 1121, and 1124 that Glaxo seeks to suppress as a basis for our decision. Accordingly, we need not and have not decided Glaxo miscellaneous motion 11. Glaxo miscellaneous motion 11 is DISMISSED as moot.

Glaxo miscellaneous motion 12

Glaxo miscellaneous motion 12 is treated as a motion to suppress evidence (FF 23). Glaxo moves to suppress Cabilly specific portions of Cabilly Exhibits 1100, 1167, 1120, 1169, 1121, 1168, 1124, 1165, 1166, and 1172 (Paper 178 at 2-3). We have not relied upon the portions of Cabilly Exhibits 1100, 1167, 1120, 1169, 1121, 1168, 1124, 1165, 1166, and 1172 that Glaxo seeks to suppress as a basis for our decision. Accordingly, we need not and have not decided Glaxo miscellaneous motion 12. Glaxo miscellaneous motion 12 is DISMISSED as moot.

D. Cabilly preliminary motions

Cabilly preliminary motions 1-6

Cabilly preliminary motions 1-6 seek judgment that the Glaxo involved claims are unpatentable. Since Glaxo cannot prevail on priority in the interference, we need not and have

not decided if the Glaxo involved claims are unpatentable on any other basis. Cabilly preliminary motions 1-6 are DISMISSED as moot.

Cabilly preliminary motions 7-9

Cabilly preliminary motion 7 to redefine the interference by adding proposed claims 61-67 to the '611 application was filed by Cabilly under 37 CFR 1.633(i) in response to Glaxo preliminary motions. 37 CFR § 1.633(i) allows a party to file a preliminary motion to redefine the interfering subject matter in response to an opponent's preliminary motion under § 1.633(a), § 1.633(b), or § 1.633(g). Since we do not grant any Glaxo motion filed under § 1.633(a), § 1.633(b), or § 1.633(g), we need not and have not decided Cabilly preliminary motion 7.

Cabilly preliminary motions 8 and 9 seek priority benefit of the '457 and '419 applications as to proposed claims 61-67. Since we do not decide to add claims 61-67 to the '611 application, we need not and have not decided Cabilly preliminary motions 8 and 9.

Cabilly preliminary motions 7-9 are DISMISSED as moot.

E. Other Cabilly motions

Cabilly's first motion to suppress evidence

In its first motion to suppress evidence (Paper 167), Cabilly moves to suppress Glaxo Exhibits 2033, 2231, 2088, 2230, 2028, 2157, 2220, 2098, 2148, 2103, and 2159. To the extent we relied upon Glaxo Exhibits 2033, 2231, 2088, 2230, 2028, 2157, 2220, 2098, 2148, 2103, and 2159, we did not find the exhibits persuasive in supporting Glaxo's position. Therefore, the suppression of the exhibits would not change our decision and therefore we need not, and have not, decided Cabilly's first motion to suppress. Cabilly's first motion to suppress is DISMISSED as moot.

Cabilly's second motion to suppress evidence

In its second motion to suppress evidence (Paper 208), Cabilly moves to suppress the Decision of the EPO in case number T1211/97-3.3.4. To the extent we relied upon the Decision of the EPO in case number T1211/97-3.3.4, we did not find the Decision persuasive in supporting Glaxo's position. Therefore, the suppression of the Decision would not change our decision and therefore we need not, and have not, decided Cabilly's second motion to suppress. Cabilly's second motion to suppress is DISMISSED as moot.

F. Redeclaration

In the order below the interference is redeclared only to the extent that Count 2 is substituted for Count 1. Since Glaxo has not alleged a conception date prior to the filing date of Cabilly's '419 application filing date, we need not and have not decided whether Cabilly is entitled to the priority benefit of its '457 application or whether Glaxo is entitled to the priority benefit of its 08/046,893, 08/943,146, or 07/777,730 applications for Count 2.

In its preliminary motion 5, Glaxo did not sufficiently explain why the claims that are designated as corresponding to Count 1 should not also be designated as corresponding to Count 2.[24] Nonetheless, when we evaluate the Glaxo claims, we determine that all the Glaxo claims are appropriately designated as corresponding to Count 2. Thus, we do not alter the claim designations found in the Notice Declaring Interference (Paper 1 at 49).

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[24] We again note that Glaxo states that certain claims of its involved patents should not correspond to Count 2 "for the reasons set forth in GWI Preliminary Motions 6-9. The arguments from Glaxo preliminary motions 6-9 may not be incorporated into Glaxo preliminary motion 5 by reference to preliminary motions 6-9. Moreover, Glaxo preliminary motions 6-9 are dismissed as moot. Thus, we have not considered Glaxo's arguments in Glaxo preliminary motions 6-9.

IV. ORDER

Upon consideration of the record of the interference and for reasons given, it is

1. Redeclaration:

ORDERED that the interference is redeclared only to the extent that the Count 2, set out below and which is identical to Glaxo proposed Count 2, is substituted for Count 1:

Count 2

The invention of claim 1 of U.S. Patent 5,545,403; Claim 1 of U.S. Patent 5,545,404; Claim 1 of U.S. Patent 5,545,405; Claim 53 of Cabilly Application No., 08/909,611; or Claim 55 of Cabilly Application No. 08/909,611;

2. Glaxo preliminary and other motions:

FURTHER ORDERED that:

Glaxo preliminary motion 5 is GRANTED-IN-PART , DENIED-IN-PART, and DISMISSED-IN-PART;

Glaxo preliminary motions 3, 10 and 11 are DENIED;

Glaxo preliminary motions 1, 2, 4, 6-9, and 14 are DISMISSED as moot;

Glaxo preliminary motions 12 and 13 are DISMISSED as improper;

Glaxo miscellaneous motions 5, 8, and 10-12 are DISMISSED as moot;

3. Cabilly preliminary and other motions:

FURTHER ORDERED that Cabilly preliminary motions 1-9 and the Cabilly motions to suppress are DISMISSED as moot;

4. Final Judgment:

FURTHER ORDERED that judgment on priority as to Count 2, the sole count in the interference, is awarded against junior party Glaxo Wellcome, Inc.;

FURTHER ORDERED that junior party Glaxo Wellcome, Inc., is not entitled to a patent containing claims 1-7 of patent 5,545,403 which correspond to proposed Count 2;

FURTHER ORDERED that junior party Glaxo Wellcome, Inc., is not entitled to a patent containing claims 1-7 of patent 5,545,404 which correspond to proposed Count 2;

FURTHER ORDERED that junior party Glaxo Wellcome, Inc., is not entitled to a patent containing claims 1-9 of patent 5,545,405 which correspond to proposed Count 2;

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of Glaxo's 5,545,403, 5,545,404, and 5,545,405 patents and Cabilly's 08/909,611 application; and

FURTHER ORDERED that if there is a settlement agreement, the parties are directed to 35 USC § 135(c) and 37 CFR § 1.666;

RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

SALLY GARDNER-LANE
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

cc (via Federal Express):

Counsel for Glaxo Wellcome, Inc.:

Gerald M. Murphy, Jr.
Raymond C. Stewart
BIRCH, STEWART, KOLASCH, & BIRCH, LLP
8110 Gatehouse Rd., Ste. 500 East
Falls Church, Va. 22042

Tel: 703-205-8000
Fax: 703-205-8050 or 8060

Counsel for Cabilly (real party in interest, Genentech, Inc.):

Steven B. Kelber
PIPER, MARBURY, RUDNICK & WOLFE, LLP
1200 Nineteenth St., N.W.
Washington, D.C. 20036-2430

Tel: 202-861-3900
Fax: 202-223-2085

EXHIBIT A

CURRICULUM VITAE

NAME: **Mark Robert LIFELY, PhD**

ADDRESS: Department of Cell Biology
Wellcome Research Laboratories
Langley Court
Beckenham
Kent BR3 3BS

TELEPHONE: 081-658-2211 Ext. 6343

DATE OF BIRTH: 4th August, 1953

PLACE OF BIRTH: Derby, England

NATIONALITY: British

ACADEMIC AND CAREER DETAILS

1964 - 1971 Gravesend Boys Grammar School, Gravesend, Kent.

1971 - 1975 Royal Holloway College, University of London, Egham, Surrey.

B.Sc. First Class Joint Honours in Chemistry and Mathematics (Harrison Prize)

1975 - 1978 Department of Microbiological Chemistry, University of Newcastle, Newcastle upon Tyne.

Ph.D. Thesis The Teichuronic Acid from cell walls of *Bacillus licheniformis* ATCC 9945.

Supervisors Professor Sir J. Baddiley and Dr. E. Tarelli.

The unique structure of Teichuronic acid, a cell wall polysaccharide of *Bacillus licheniformis*, was determined by using a battery of techniques which included methylation analysis, periodate oxidation and partial acid hydrolysis: products were identified by gas-liquid chromatography and mass spectrometry, and ^{13}C- and ^{1}H- nuclear magnetic resonance were used for confirmatory analysis.

1978 - Present Senior Research Scientist
Wellcome Research Laboratories, Langley Court, Beckenham, Kent BR3 3BS.

Miscellaneous	Member of the Medical Research Council Committee on the Development of Vaccines and Immunisation Procedures: Subcommittee on Polysaccharide Vaccines.
	Wellcome Co-ordinator and Representative on the SERC LINK Scheme with Dundee University on 'Bioactive Oligosaccharides'
	Patent Evaluator for 'Current Opinion in Therapeutic Patents'

CAREER AT WELLCOME (1978-PRESENT)

1978-1985	Research Scientist responsible for chemistry and microbiology relating to meningococcal vaccines. This included responsibility for co-ordination of research in Physical Chemistry and Bacteriology.
1985-1989	Senior Research Scientist responsible for Project K27 (Meningococcal B Vaccine) and for Programme 32L (Polysaccharide Vaccines).
1989-Present	Senior Research Scientist responsible for Programme 34G (Myeloma CAMPATH-1H).

Milestones:

Programme 32L (Details in Appendix I)

1980: Discovery of chemical instability of meningococcal B polysaccharide.

1981: Production of monoclonal antibodies against meningococcal B polysaccharide. which were subsequently developed for use in the Wellcome Diagnostics '**WELLCOGEN**' kit.

1982. Initial development of a meningococcal B vaccine.

1984: Research-led determination of three-dimensional structure of the meningococcal B polysaccharide. and discovery of metal ions useful in stabilisation of the vaccine. Two Patents were filed in this area.

1985: Initiation of Project K27 on Meningococcal B Vaccine.

Project K27 (Details in Appendix I)

1986: Development of process to 20L scale achieved (estimated 20,000 doses vaccine).

1987: CTX obtained and Phase I/II volunteer study approved.

1988: Volunteer Study successfully completed. Follow-up study initiated.

1989: Follow-up study completed. Vaccine shown to be immunogenic in man.

Programme 34G (Details in Appendix II)

1991: Programme Proposal on myeloma CAMPATH-1H accepted.

1992: Nine engineered myeloma lines expressing CAMPATH-1H transferred to Development. Protein-free media supporting growth of these lines have been developed. Preliminary Patents on growth media are being prepared. Assays have been developed.

AREAS OF EXPERTISE

My research experience is multidisciplinary, and includes chemistry, immunology, cell biology and microbiology. This has necessitated the development, use and understanding of a wide variety of skills and techniques involved in product identification, characterisation and purification, immunological assays and monoclonal antibody technology (Details in Appendix III).

My management experience over the last seven years has included the leadership of a Project (K27: 1985-1989) and two research Programmes (32L:1985-1990; 34G:1991-Present). In addition, in 1990, I assumed responsibility for the co-ordination and organisation of assays for CAMPATH-1H.

In leading Project K27 for four years through to completion of Phase I/II clinical studies, I acquired an understanding of many aspects of the organisation of the Company through co-ordination of the activities of disparate groups, including DMS, Quality Assurance, Development, Production, PCU, Marketing, Finance, DSE, GPA and IDRA. The position also required that progress was regularly communicated to senior management through written and oral presentations.

REFEREES

Dr. C. Moreno
MRC Tuberculosis and Related Infections Unit
Hammersmith Hospital
Ducane Road
London W12 0HS

Dr. K. Powell
Head. Department of Cell Biology
Wellcome Research Laboratories
Langley Court
Beckenham
Kent BR3 3BS

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3. M.R. Lifely and F.H. Cottee. 1982. Formation and identification of two novel anhydro compounds obtained by methanolysis of N-acetylneuraminic acid and carboxyl-reduced. meningococcal B polysaccharide. Carbohydr. Res. **107**:187-197.

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9. M.R. Lifely. Polysaccharide Vaccines (Invited Lecture). NATO ASI "New-Generation Vaccines: The Role of Basic Immunology" Cape Sounion Beach. Greece. June 24-July 5. 1992.

APPENDIX I

For a number of years, my objective was to develop and direct a Project (K27) and Programme (32L) on bacterial polysaccharides for use as human vaccines. This involved: (i) identification, extraction, purification and characterisation of capsular polysaccharides and outer membrane proteins from different pathogenic organisms, and subsequent modifications of the polymers to increase their immunogenicity; (ii) Testing of candidate vaccines in animal models for immunogenicity and protection from disease; and (iii) Determination of human defence mechanisms that are important in the response to and prevention of disease.

Meningitis, caused by Group B meningococci, was recognised from the outset of our programme as a serious disease, and our primary objectives became, firstly, a rapid, sensitive and reliable diagnostic reagent for detecting the disease and, secondly, a vaccine through modification of the capsular B polysaccharide which was known to be poorly immunogenic. The first objective was achieved when a commercial latex reagent '**Wellcogen**' was introduced to the market place by Wellcome in 1986. This was the result of successful collaboration between our programme and Wellcome Diagnostics in production and characterisation of monoclonal antibodies useful for the detection of meningococcal B polysaccharide. The pursuit of a vaccine required an inter-disciplinary approach involving Carbohydrate Chemistry, Immunology and Physical Chemistry. We succeeded in demonstrating that the poor immunogenicity of the polysaccharide was linked to its three dimensional structure. This required probing the polysaccharide structure through immunological techniques using specific antibodies, and physico-chemical techniques using primarily ^{13}C- and ^{1}H-n.m.r. and molecular modelling through computer graphics, that led to a candidate vaccine which was immunogenic and protective in an animal model. Leading from this I became responsible in 1985 for management of a major development project on the meningococcal B vaccine for use in a human volunteer trial. This required an understanding of many aspects of the organisation of the company, and involved coordination between a number of groups, including Clinical, Quality Assurance, Development, Production, Project Planning, Marketing, Finance Toxicology, Patents and Agreements, Regulatory Affairs and Commercial Development. It has also been necessary on occasion to travel worldwide to negotiate with third parties over commercial arrangements for carbohydrate vaccine products.

APPENDIX II

In 1990, in relation to a humanised monoclonal antibody (CAMPATH-1H) against lymphoid malignancies, I become responsible for: (i) Establishing and developing a research base, the primary aim of which was to determine the structure of the CAMPATH-1 antigen and its antigenic epitopes (ii) Co-ordination and organisation of both binding and functional assays for CAMPATH-1H; and (iii) Direct involvement in such aspects as fermentation, purification, formulation and stability, and characterisation of CAMPATH-1H.

In 1991, I assumed responsibilities for Programme 34G (Myeloma CAMPATH-1H) with the objective of developing a stable myeloma cell line producing CAMPATH-1H at >20µg/mL for comparison with CHO-derived CAMPATH-1H. Responsibilities included co-ordinating the activities in engineering the cell lines, adapting the engineered lines for growth in protein-free media, liaison with the Development Division on transfer of cell lines and timings for process scale-up, discussion with DSE on cynomolgus monkey studies, and development of assays for biological activity testing.

APPENDIX III

My research experience in microbiology includes batch and continuous culture fermentation of Gram-positive and Gram-negative bacteria under different growth conditions. laying down and testing of seed cultures and use of aseptic techniques. My research experience in carbohydrate and protein chemistry ranges from extraction, purification and characterisation, to degradation and modification of antigens from prokaryotic and eukaryotic cells. My research experience in immunology involves testing of carbohydrate vaccines for immunogenicity and biological efficacy, exploration of immune defence mechanisms and determination of structure-function relationships through immunological and physico-chemical means. Specifically, this involves experience in the following areas: polyacrylamide gel electrophoresis and immunoblotting or T-cell blotting; epitope mapping using specific monoclonal antibodies; solid and liquid phase immunological techniques for quantification and specificity of antibodies and antigens; antibody functional assays including bactericidal and opsonic activity, animal models of protection; liquid chromatography (ion-exchange, gel filtration, hydrophobic, affinity); gas-liquid chromatography (g.l.c); g.l.c. - mass spectrometry; ^{13}C- and ^{1}H- n.m.r spectroscopy; infra-red spectrophotometry; colorimetric assays; methylation analysis; modification of carbohydrates through periodate oxidation, carboxyl reduction, N-deacetylation, N and O-acylation, introduction of reactive groups and coupling to carrier molecules, fluorescence and radiolabelling of carbohydrates and proteins.